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**Moderator: Morgan Jackson, M.D.
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Good Afternoon. My name is Morgan Jackson. I'm at the Center for Complementary and Alternative Medicine (NCCAM), National Institutes of Health. I'm here with Dr. Peter Kozel. We are conducting a technical assistance conference call for applicants to Program Announcement 05-152, which had a receipt date on November 14, 2005.

By now you all should have received your summary statements or have access to your summary statements. Today we're not going to discuss summary statements individually, but will discuss general aspects of the review and reapplication process. I am happy to speak with you individually about your summary statements. In order to do that, I ask that you send me an email to make an appointment for a telephone conversation.

Joining us on the phone also is Dr. Martin Goldrosen, who is the Acting Director of the Division of Extramural Activities (DEA) at NCCAM. For most of you, it might mean Drug Enforcement Agency, but here at NCCAM, Dr. Goldrosen is our DEA officer and it doesn't mean Drug Enforcement Activity.

The purpose of the conference call is to provide technical assistance for principal investigators to improve their chances of funding in the next round, and the agenda will consists of five parts.

First, Dr. Goldrosen will give an overview of how a grant application is reviewed and the mechanics of review. Then, he will talk about how a summary statement is prepared. I will then discuss a recommended process for you to use in addressing the reviewers' comments and preparing a revised application.

Following that, Dr. Goldrosen will talk about how revised applications are reviewed, should you choose to resubmit. Finally, we'll take questions. That being said, I'd like to turn it over to Dr. Goldrosen.

Martin Goldrosen: Good afternoon everyone. I'm going talk, as Dr. Jackson pointed out, about the initial peer review process.

As you are aware, the initial scientific review group's responsibility is to provide an initial assessment of the scientific merit of a new application. They provided you with a priority score based on the five specific review criteria. [Those criteria are: Significance, Approach, Innovation, Investigators, and Environment]. They also potentially identify human subject concerns, animal welfare concerns and biohazard issues.

Who are the people who typically review your application? These people more often than not are individuals who have received funding from us or from other NIH Institutes and Centers. They are working in a CAM modality that is reflective of what you're doing. There also are individuals on the committee who are familiar with the disease that you're studying as well as the research methods proposed. So in effect your application is looked at

from all different angles. You may have noticed that sometimes there'll be a divergence of opinions between the individual critiques. That represents the fact that the individuals looking at your application really look at it from different perspectives.

Let me tell you briefly what happens at the meeting. Typically, there are 20 to 30 peer reviewers on the panel. When the applications are initially brought up for discussion, we use a triage procedure. In the triage procedure, the scientific review administrator (SRA) asks the reviewers to give us their scores and their critiques before the meeting. The SRA then prepares a composite score to identify all those applications which are in the upper half and those which are in the lower half of the scoring range.

Typically, applications in the lower half will be unscored. They will not be discussed, so a resume of discussion will not be prepared. That is not to say that your application has a lot of issues. All we're saying to you at this point is that your application is not as competitive as the other ones in this review cycle. Once the reviewers decide which applications are competitive and which are not competitive, discussion begins of the competitive applications.

There are at least three reviewers who are specifically assigned to each application. Each reviewer proposes a score in advance of discussing your application to see the general range of scores. If all the scores are very close [within a narrow range which means that all the reviewers agree on the scoring of the application], the application will not get as much discussion as those applications where the range is farther apart [and there is disagreement about the application]. Then the primary reviewer presents a critique of your application. The secondary reviewer and subsequent reviewers or readers add any additional information. We ask reviewers not to repeat each other when there is agreement.

The discussion of the application is opened up [to the entire committee] to see primarily if a consensus can be achieved. Sometimes it happens. Other times it doesn't happen. You may end up with a score that reflects the diversity of opinion. Once the discussion is complete, all reviewers score the application.

If there are any reviewers who are in conflict with your application - that is primarily institutional conflict - they are not allowed to be in the room during the discussion of the application but come back after your application has been discussed.

As you are aware, reviewers give applications a score between 1.0 and 5.0 with 1 being the best, 5 being the worse. The midpoint of the range is 3.0. Typically, we tell the reviewers to score an application as 3.0 if the strengths and the weaknesses are equal. Anything between 1.0 and 3.0 indicates that your application has more strengths than weaknesses. Application scores between 3.0 and 5.0 indicate that there are more weaknesses than strengths.

If you get a NRF (not recommended for funding), it tells us that there is a serious issue with the way the protection of human subjects has been handled. The closer you get to 1.0, the implication is that there are fewer weaknesses and the weaknesses are highly addressable, particularly if your application scored between 1.1 and 1.5. Once we get to around the 2.0 level, it is an indication that your application needs to be reworked even though there are significant strengths to what you proposed to do. That's basically how the peer review process works in general.

Let me tell you a little bit about the summary statement. The summary statement is prepared by the SRA. You will receive the individual critiques essentially verbatim. We ask the reviewers to make corrections to the

critiques if their opinion has changed between the time they wrote it and the review meeting itself.

What NCCAM staff wants you to take home from the summary statements is the fact that the resume is part of the document that truly summarizes the discussion. We try to capture the essence of the discussion in the resume. If there are discrepancies between what the resume says and what the individual critiques say, I would choose the resume as the basis for your response if you do intend to submit an amended application.

What you should see is a balance between what the resume says and the scores. The score reflects the overall resume. I'll stop here and let Dr. Jackson continue on.

Morgan Jackson: Thank you, Dr. Goldrosen.

I want to emphasize a few points that Dr. Goldrosen made that might help to clarify and elaborate on some aspects of the review process. Because this is a mechanism that we call a PAR, a special type of program announcement, applications were sent to the usual study sections for NCCAM. As a result, they were considered in the context of all other applications received by NCCAM. As Dr. Goldrosen mentioned, approximately half of the applications are unscored and those are thought to be in the lower half of the group of applications presented for review.

As a result of this conversation, I'll infer that everybody who is participating has an application that was not funded and did not score in a range to be funded. What I have to ask you to do is to take a deep breath once you look at the summary statement and count to 10 or perhaps 20 or perhaps 100 or whatever number is necessary for you to get over the feelings that may have

been generated by the apparent rejection. You should then come back and review the comments of the study section contained in the summary statement.

I'd like to talk about the summary statement. First of all, I'll talk about the structure of the summary statement. On the first page, you will see my name and my contact information, the application number, your name and address, the name of the NIH review group, the date on which the application was reviewed, the date of the National Advisory Council round to which it will go for a second level of review, the title of your application, and under that, a number following the phrase "SRG Action." This number is your application's priority score. If the application is unscored, there will be asterisks here instead of a number. There also are several other numbers -- numerical codes that are very important in determining the fundability of the application. These codes relate to issues surrounding the inclusion of women, the inclusion of minority participants, the inclusion of children, the protection of human subjects, and if animals are included in the application, protections for animals as well. There will be summary budget information based on the application as it was submitted.

Following the first page for those applications that were scored, there will be a paragraph called "Resume and Summary of Discussion." As Dr. Goldrosen mentioned, this paragraph is written by the scientific review administrator (SRA) and is a concise summary of the actual discussion that occurred. For those applications that are unscored, this section (Resume and Summary of Discussion) does not exist. Instead, the summary statement goes straight to the next section, "Description," and in parenthesis, it says, provided by applicant. This is a verbatim copy of the abstract that was part of the submitted application. After the description provided by applicants, you'll get to individual sections called Critiques. Critiques are prepared by the

reviewers, and are numbered Critiques 1, 2, 3, and occasionally, Critique 4. In each critique you will see sections called Significance, Approach, Innovation, Investigators, and Environment.

Each of the reviewers will comment on the protection of human subjects, the plan for inclusion of women, the plan for inclusion of minorities, and the plan for inclusion of children. There will then be an overall evaluation paragraph and a budget section before or after that. At the end of the summary statement, you'll see information regarding a summary determination by the committee regarding human subjects protection, the inclusion plan, as well as the committee budget recommendation. The final pages of the summary statement are the meeting roster where the scientific review administrator will be identified along with the chair of the review committee and members of the panel.

As Dr. Goldrosen summarized the process, each application received by the committee is assigned to a subset of panel members who are responsible for preparing written critiques that become part of the summary statement and providing preliminary scores for the applications. Based on the preliminary scores, applications are triaged. Those scoring in the lower half of the group are not discussed although the written critique is still available. Those in the upper half of the group will be discussed. If a single member of the committee wants the application to be discussed, then the application is discussed. The motion for triaging or not discussing an application must be approved unanimously by the entire committee.

The reviewers who have provided the written critics are then responsible for leading the discussion that is held. It's very important for you to realize that not every member of the review panel will have read your entire application. Many of the people participating in the review committee will only have

scanned it. I need to ask you to make it easy on yourself and for the reviewers by writing an application that is clear, concise, understandable, and organized so that information in the application is easy to find.

It's not unusual in the study section for reviewers who do not have intimate familiarity with the application to look for specific points that might have come up in discussion, and if they can find the points, sometimes they can refute a misperception that is held by people in the room. Also, I need to emphasize the fact that in your application, you're writing for a very diverse audience. Not all the reviewers on the committee will be familiar with your field of research and therefore you need to write such that those reviewers who are unfamiliar with the topic or the field can be educated by the application.

Remember, the principal investigator bears the burden of proof regarding the significance and all other aspects of the project. Your application is a document of persuasion as well as a document of information. If there's a circumstance where an application has not received a score that can be considered fundable, then you should consider the application as being insufficiently persuasive and need to think about how it can be strengthened in order to make it more persuasive. The application should contain enough detail to satisfy the members of the panel who are experts in the field, but it also needs to provide enough background information to bring the generalist and others up to speed.

Once you've received your summary statement, and also once you've gotten over the emotional reaction to not getting the score that you want, I suggest that you sit down and make a list of all of the comments in the critique, especially the critical comments. The reason you need to do this is because in

preparing a revised application and submitting it, it is critical that you address each and every one of the comments raised in the summary statement.

You need to respond to all of the suggestions and comments even if you don't agree with them. If there's one that you don't agree with, you do not have to change the approach. But as I mentioned earlier, you need to recognize that your application was insufficiently persuasive and you need to strengthen the justifications for choosing the course of action that you chose. It is important though that you address each of the reviewer's comments in working to make your document more persuasive.

Grantsmanship frequently goes above and beyond doing good science. It has a lot to do with understanding the psychology of the reviewers. It is critical that you always treat reviewers' comments respectfully.

I was looking at a document that came to me recently, fortunately, just to me personally and not to the entire review committee, in which the investigator stated that perhaps the reviewers are not familiar with the field of cardiology. That comment would not be well-received by a review committee. Whether or not it is true, it may be perceived as patronizing and adversely affect the application's chances.

It really is important to avoid being patronizing and avoid being argumentative. I can't tell you how many times reviewers of revised applications comment on the tone of the document of the revised application as well as the introduction. All other things being equal, the revised applications that seem to do best are those in which the principal investigator expresses appreciation for the critiques, and recognizes that the purpose of the review is to make sure that the Center is supporting good science and that the

investigator has the best chance of accomplishing the results of the work he or she is undertaking.

It's important for the principal investigator (PI) to address succinctly the specific points outlined in the summary statement. It's also important to fix the identified weaknesses, but I cannot emphasize this next point enough. You need to take the opportunity to improve the applications generally and not merely limit revisions to the comments that are articulated in the summary statement.

Unfortunately, it does happen that when a revised application is submitted, new people on the review committee sometimes raise new concerns and comments. So it is critical than in revising an application, the PI do whatever he or she can do to identify all the weaknesses, even though they go beyond comments that were made in the summary statement. Subsequent applications will be reviewed alongside this summary statement, and reviewers will comment on the degree to which the revised application addresses those comments.

Now, let me address a question that has come up on several occasions. You do have the choice of resubmitting your application using one of the regular receipt dates -- February 1, June 1 and October 1. However, NCCAM strongly encourages you to use the November 14, 2006, and November 14, 2007, receipt dates to submit revisions of these applications.

I'm going to repeat that we're focusing in this conference call only on general comments relating to the process of addressing critiques in a summary statement. However, when you and I talk about your summary statement, I will have gone through and identified the points that I saw that I think need to be addressed in a revised application. I would ask you in reviewing your

summary statement that you also go through and identify the points in the summary statement that you think need to be addressed in the revised application.

That being said, I'd like to turn it back over to Dr. Goldrosen to talk about how the revised application would be reviewed.

Martin Goldrosen: I would like to elaborate on some points that Dr. Jackson has made, specifically the idea that it is up to you to make your case in your application.

You can't assume anything in the process. I would not make any assumptions, from the simplest to the most complex. If there is an important line of reasoning that's part of your argument, it should be stated clearly.

The question is, how do you address changes? Well, first of all, you have to address changes in the introduction section. It is here that you have the opportunity to state whether you agree or disagree with the comments in the summary statement. You should then state how you're going to proceed and what changes you have made. That's Item No. 1.

Item No. 2: In the text of your revised application, you should highlight the changes you made. You can highlight it by underlining it, putting the text in bold or italic typeface, or you can put a bar on the side of your text. You should state in your introduction how the changes are annotated in the text.

One other general idea before I forget. Once you have rewritten your application, if you have not already done so, I think it's a good idea to have somebody you know who works in your field read it before you resubmit it. It's a very good idea much the same way when you draft a manuscript for publication in a journal; you tend to try to find some other individuals who work in your area to read it before you submit it for review. The same thing

applies to grant applications. You should try to find people who are familiar with your work and who can review the application for technical flaws, typing errors, inconsistencies and comment on your overall scientific approach.

It's always good to have a buffer between you and the review committee.

So let's now talk about what happens with the review committee. Your revised application comes back in and generally the discussion starts with the SRA or chair stating what your score was during your prior review. The first question that the chair typically asks is, how did the applicant respond to the critiques? It is from this perspective that the discussion of your revised application is framed. As Dr. Jackson said, if you've responded to the previous reviewers concerns and no other issues are brought up, then you should see a positive movement in your score.

We try and bring back, either in person or by phone, the same reviewers that have looked at your application, but we cannot guarantee to do so in part because we can't control the schedules of individual reviewers. We try to impart some degree of continuity to the process. Generally, if the score doesn't improve or gets worse, we try to get reviewers to give explicit reasons for this happening. I'll stop here and let Dr. Jackson take over again.

Morgan Jackson: Thanks again, Dr. Goldrosen. In the next five minutes, I want to emphasize a couple of points that I had come across generally relating to grantsmanship. Then we will turn it over to the audience for questions.

I have to emphasize that for the next receipt date, November 14, 2006, you will be required to use the electronic submission procedure with the new SF 424 application documents. We plan to have a conference call later in the summer focusing on that process, which is a new one for all of us. We hope this will ease the transition into the electronic format.

I need to emphasize that the research project optimally is hypothesis-driven. Repeatedly we find that projects that are hypothesis driven are more successful than ones that are not. It's also critical for you, your colleagues, and your institution to ask, "Will the project that I'm designing answer the questions the application asked?"

It's incredibly important also for you to describe how the proposed research addresses a gap or a problem area. In reviewing the literature, you need to impress the reviewers with your up-to-date knowledge of the field by referencing not only work from your laboratory if appropriate, but also work from competitors' labs and include as well work that does not agree with your hypothesis.

Right now, I'm dealing with an issue where there was an important paper in the literature that had a different perspective from that which the applicant was arguing. Because it had a different perspective, he did not include it his application. I'm afraid that that single point probably resulted in his not getting a score that we would be able to fund. Please keep this point in mind.

Dr. Goldrosen mentioned the importance of looking within your institution for internal peer-review prior to submission. I had sent an email out earlier that suggested that you find out whether your institutions or departments have programs or resources to assist with the NIH grant application process. Frequently, the Office of Sponsored Programs at your institution has resources that can assist you with internal review of your applications. In addition, it's important to identify individuals at your institution who can assist you with this process. In a previous email I sent a link to the NIH (CRISP) database (<http://crisp.cit.nih.gov>) to assist you in identifying those individuals.

I'm going to stop there and open it up to questions that people might have.
The time now is about 2:33. We'll be stopping no later than 3 o'clock, and
I'm available for questions that people might have.

(Participant 1): I don't have an eRA number yet. I have applied for one, but I haven't
received one, so I haven't had the opportunity to see my review.

Morgan Jackson: Send me an email and we can do one of two things. I can either fax you your
summary statement or email it to you. If I send it by email, it does pose the
risk of other people being able to access the document. If you want me to, I
can fax it to you. If you send me an email letting me know how you'd like for
me to send it to you, I can make sure that you get it.

(Participant 1): Thank you very much. Thank you for organizing this. This has really been
helpful to me.

Morgan Jackson: Other questions?

(Participant 2): I have a quick question. What was the fundable score for this round?

Morgan Jackson: The information on NCCAM's Web site indicates that at this point in time,
our fundable score is 150 or better, better being lower. A 100 is a perfect
score. There may have once been someone who submitted an application that
received a score of 100, but not in my short tenure here at NIH. It's possible
at the end of the year if funds remain, we will be able to move the so-called
pay lines to a slightly higher score, but I do not expect it moving materially.

(Participant 2): So the target score is 150 and better?

Morgan Jackson: Correct.

(Participant 2): Okay. So what's the percentage of applications that achieved that score or that range of scores?

Morgan Jackson: Because of the number of applications that we received, NCCAM is usually funding in the range of 1 in 8 to 1 in 10 applications, approximately. I've been reading some articles in the scientific literature, some of them dating from 1999 and 2000, that talked about NIH funding 25% or perhaps 30% of applications. While that might still be true for some of the Institutes and Centers at NIH, I'm not certain that it, in fact, is true presently.

Peter Kozel I think that Dr. Goldrosen might be able to confirm this, but it's my understanding that the ratios Dr. Jackson described - between 1 and 8 and 1 and 10 for NCCAM - are the fairly common throughout the NIH this fiscal year. Given NIH's budget in future years, it seems likely that those levels will not improve over the near term.

(Participant 3): Okay. You strongly suggested that we should send the revised application on November 14. However, I think that we are ready to answer effectively all of the issues raised by the reviewers and we would like to do it much sooner than that. Is there any specific reason that you're recommending the November 14 receipt date?

Morgan Jackson: Dr. Goldrosen, would you like to address that question?

Martin Goldrosen: There are some subtle differences between this program announcement and our generic R21 program announcements. Specifically, your announcement had a minority health or health disparity component to it. The application had to indicate that it came from selected institutions and this information may not be relevant to a review by any other committee. If you were to submit your

application to one of the other, standard R21 receipt dates, I'm concerned that the reviewers who receive your amended applications and initial critique will not really know what to make of the uniqueness of this program announcement. For that reason, I would encourage you to stick to November 14. If you come in earlier, there are some risks of reviewers misunderstanding what the initiative was all about.

Morgan Jackson: The other thing I would say to the investigator is that the NIH used to permit unlimited numbers of revisions of an application. However, at this point in time, you're allowed only two revisions. Furthermore, the summary statements have only become available in the last two weeks. I would have to argue that it would be extraordinarily unlikely for most investigators with whom I've had experience in my short tenure here at NIH to be able to receive the summary statements and make material changes in the applications sufficient to address all issues raised in those summary statements in less than a two-week period of time.

I really think that it will be important for you to undertake the internal review process and to get a revised application reviewed by as many individuals at your institution with whom you can work to make sure that each time you submit an application, it is the strongest application that you possibly can submit. Remember that you will be submitting an A1 application next time, and this next submission will be the next to last time that you will be allowed to submit that application. One of the reasons we're encouraging people to take the time to develop a strong application is to make sure that they have the best chance for getting funded in the end.

(Participant 3): Thank you very much.

Peter Kozel: If I could just point one thing out. Dr. Jackson has a very appropriate saying: When identifying individuals to help you go over your application, you should look first to your friends. But then you should go to your enemies because it is your enemies who will give you an analysis of your application that is closer to that which a NCCAM or NIH review group will give.

It is imperative that you get a range of individuals to look over your application, including individuals who are outside of your immediate field of research, because not everybody on the review panel will be an expert in your particular area.

It is important that you take your time to fully solicit and take advantage of the range of resources and opportunities that you have and not be expeditious in submitting a revised application. It takes most people two weeks just to actually submit an application to the new electronic system. As for completely revising the application in a two-week period time, maybe somebody could do it, but I think we'd all like to meet that person.

Morgan Jackson: Thank you, Dr. Kozel.

Morgan Jackson: Are there other questions at this time?

(Participant 4): I looked for my summary statement and could not find the summary statement or the score. Does that mean that we just didn't receive a score or are we looking in the wrong place?

Morgan Jackson: All the summary statements are available. What I suggest is that you send me an email. I previously had found the email addresses and telephone numbers for the Help Desks for the different components -- we now have the NIH Commons and I think there might be the eRA Commons and there are other

components. I have to confess, I am not knowledgeable about how people access the different aspects of the NIH system from the outside because I've never been in the position of doing that. Send me an email and I will see what I can do about finding the Help Desk Contact Information that should assist you in being able to gain access to the system.

(Participant 4): Thank you very much.

Morgan Jackson: Any other questions? Going once. Any other questions? Going Twice. It's now 2:45. I've accomplished the things that I wanted to accomplish in this conference call. I hope it's been helpful for people. You will recall that with the program announcement, we had a link on the Web site that identifies additional information and other resources. We'll be creating a similar link for this program announcement.

One of the things I need to tell you is that because we are changing to the electronic format, this program announcement was identified as PAR-05-152, but now it is called PAR-06-372.

In addition, the format of our research page has changed. If you go to the NCCAM Research Web pages, do a search using keywords "Minority Health" or "Health Disparities" to bring up these program announcements.

We will put a transcript of the conference call on the Additional Information page. As I've mentioned previously, we're planning additional conference calls to address a range of subjects associated with revising and resubmitting the applications including one that will focus on electronic submission and the SF 424 applications.

I thank you all for your time and attention this afternoon. I'll make one last solicitation of questions.

(Participant 6): Would you be able to tell us what percent of applications were actually funded?

Martin Goldrosen: That is confidential information, and in fact, we don't have the information currently since these applications have not gone to Council. On an annual basis, we do list on the NCCAM Website the applications that were funded in the previous year. But that information won't be available for sometime -- probably not until next January.

Morgan Jackson: If there are no other questions, I'll thank you again for your time and attention, and we will send you an email in the next couple of weeks identifying the date and the time for the next conference call.

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